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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,926	09/16/2003	Michael E. Benz	P-10909.00	2299

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EXAMINER	
SERGENT, RABON A	

ART UNIT	PAPER NUMBER
1711	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,926	BENZ ET AL.	
	Examiner	Art Unit	
	Rabon Sergent	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70,76 and 77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-70,76 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. In view of applicants' amendment to claim 77, the restriction requirement with respect o this claim has been withdrawn. Accordingly, claim 77 has been examined on the merits.

2. Claims 1-70, 76, and 77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have failed to define the term, "substantially free", as it pertains to ether, ester, and carbonate linkages. It cannot be determined what quantity of these linkages the language provides for. The issue is further aggravated by the fact that applicants specifically recite at page 16 of the specification that polymers containing these linkages may be produced.

3. Claims 1-70, 76, and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the absence of a definition of "substantially free", it cannot be determined what quantity of the ether, ester, and carbonate linkages may be present and still satisfy the claims.

4. With respect to the rejections set forth within paragraphs 2 and 3, applicants have argued that those skilled in the art would understand the meaning of the language in view of the specification. In response, the examiner has again considered the specification, including the argued passages within pages 4, 11, and 17; however, the position is maintained that the argued language has not been defined and that one of ordinary skill would not be able to determine what quantity of the argued linkages may be present and still satisfies the claims. Applicants have

further argued that the "substantially free ..." language refers to an amount of the argued linkages that produces biostable materials and that such an interpretation would be clear in view of the discussion within the Background of the Invention. In response, while the Background of the Invention refers to problems associated with the presence of such groups, no definitive guidance can be said to exist as to what quantity of these groups may be present since applicants clearly teach at pages 16 and 17 that ether-containing, ester-containing, and carbonate-containing reactants may be used to produce the polymers. It is not seen how one can reasonably conclude what quantity of the argued groups is limited by the language in view of explicit teachings that ether, ester, or carbonate linkage-containing reactants may be used. Furthermore, in view of these teachings, it cannot be reasonably argued that applicants teach away from their use. In other words, contrary to their own arguments, applicants have disclosed that biostable materials may be produced that contain the argued linkages, yet applicants have provided no teachings that clearly convey to what extent the quantity of these linkages must be limited. Accordingly, there is no means to quantitatively determine from the specification what amount of these linkages may be present while satisfying the "substantially free" language.

5. Claim 77 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps and elements, such omission amounting to gaps between the steps and elements. See MPEP § 2172.01. The omissions are summarized as follows:

Applicants have claimed that the polymeric starting compound is produced by combining monomers of Formula II or Formula III; however, it unclear how the claimed polymeric starting compound can result from one or the other formulas. It would seem that reactants that will yield both the quaternary carbon group and silicon group must be specified. Furthermore, applicants

claimed method of producing the polymeric starting compound fails to provide for the derivation of the terminal functional groups. Therefore, it would seem that steps or elements that pertain to the functionalization of the polymer are required to be claimed.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-70, 76, and 77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,984,700. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R^1 groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

8. Claims 1-70, 76, and 77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28, 30-34, 39, and 40 of copending Application No. 10/663,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R^1 groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-70, 76, and 77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-46 and 48 of copending Application No. 11/133,627. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R^1 groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-11, 14-16, and 40-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Deichert et al. ('506).

Patentees disclose polymers, including copolymers, suitable for biomedical applications wherein the polymers possess structures containing quaternary carbons and silicon-containing

groups that meet applicants' claimed structure. See abstract; column 1, lines 15-59; and columns 8-17.

12. Applicants' response has been considered; however, contrary to applicants' arguments, applicants' "segmented" limitation is inherently met in view of the copolymer disclosure. The position is taken that a copolymer inherently contains segments. Furthermore, since the disclosed structure meets applicants' claimed structure and encompasses structures of relatively high molecular weight, the position is taken that the disclosed structure can be fairly described as being a soft segment.

13. Claims 1, 2, 4, 6-16, 40, 41, 43, 45-51, and 53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Kato et al. ('325).

Patentees disclose polymers that possess structures containing quaternary carbons and silicon-containing groups that meet applicants' claimed structure. See abstract and columns 1-4. To the extent claimed, it is not seen that the language, "medical device", conveys any patentable distinction to the claims.

14. Despite applicants' arguments, since the disclosed organosiloxane polymer may be cured through reaction of the unsaturated groups, the position is taken that applicants' "segmented" characteristic is met. Furthermore, given the disclosed molecular weight of the organosiloxane polymer, the position is taken that applicants' "soft segment" limitation is met, as well.

15. Claims 1-70 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. ('254) or WO 01/07499 or WO 00/64971 or WO 98/54242, each in view of Pinchuk ('240) or EP 821973.

Each of the primary references discloses polyurethane or polyurethane-urea polymers suitable for the production of medical devices, wherein the polymer is formed from a silicon-containing polyol or polyamine wherein the silicon-containing group corresponds to that claimed and further wherein R groups containing quaternary carbons are specifically disclosed as being suitable linkages within the polyol or polyamine. Note the disclosure that the alkyl or alkylene groups may be 2,2-dimethylbutyl, 3,3-dimethylbutyl, 1,2,2-trimethylpropyl, 2,2-dimethylpentyl, 3,3-dimethylpentyl, 4,4-dimethylpentyl, and 1,1,3,3-tetramethylbutyl.

16. The primary references fail to teach a specific preference for the incorporation of these quaternary carbon-containing groups within the silicon group-containing polyol or polyamine; however, the advantages of incorporating such groups into polymer compositions to be used within medical applications was known at the time of invention. Pinchuk discloses that polymers having increased amounts of quaternary carbons are the most "medically" inert. See column 3, lines 60+ within Pinchuk ('240) and page 3, lines 36-36 of EP 821,973. Therefore, in view of these secondary teachings disclosing the benefits of incorporating quaternary carbons into the polymer chain, the position is taken that one of ordinary skill, seeking a biostable polymer, would have been motivated to select and incorporate the disclosed quaternary-carbon containing groups of the primary reference as the R groups of the silicon-containing polyols or polyamines, so as to arrive at the instant invention. Furthermore, since the primary references establish the compatibility of the quaternary carbon-containing groups with the silicon-containing groups of the polyols or polyamines, the position is taken that it further would have been obvious to incorporate increased numbers of quaternary carbons or repeating quaternary

carbon groups within the polyols or polyamines, so as to maximize the biostability of the final polymer.

17. Applicants' response has been considered. As a result, the reliance on WO 99/03863, WO 99/50327, and Benz et al. (US 2003/0125499 A1) has been withdrawn. However, the rejection has been maintained for the following reasons. Firstly, in view of the above discussion concerning the language, "substantially free of carbonate linkages", the position is taken that since no quantitative limit can be ascribed to the language and since applicants specifically disclose that carbonate linkage-containing reactants may be used to produce the polymer, the language is insufficient to distinguish the claims from the prior art. Secondly, all of the disclosed silicon-containing structures are adequate to satisfy applicants' soft segment limitation. Thirdly, despite applicants' remarks, the position is maintained that the advantages disclosed within the secondary references with respect to the incorporation of quaternary carbons within biostable polymers would have motivated one of ordinary skill to select and utilize the quaternary carbon containing species of the primary references. The position is ultimately taken that applicants' have failed to fully appreciate the teachings of the secondary references concerning the desirability of incorporating quaternary carbons into biostable polymers. These teachings coupled with the fact that the primary references specifically disclose quaternary carbon group species as linkages within the silicon-containing polymers are sufficient to render the instant invention *prima facie* obvious.

18. Claims 1-16 and 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. ('254) or WO 01/07499 or WO 00/64971 or WO 98/54242, each in view of Pinchuk ('240) or EP 821973 and further in view of Kennedy ('973).

Each of the primary references discloses polyurethane or polyurethane-urea polymers suitable for the production of medical devices, wherein the polymer is formed from a silicon-containing polyol or polyamine wherein the silicon-containing group corresponds to that claimed. See abstracts.

19. The primary references fail to provide a specific teaching regarding the incorporation of quaternary carbon-containing groups within the polymer; however, the advantages of incorporating such groups into polymer compositions to be used within medical applications was known at the time of invention. Pinchuk discloses that polymers having increased amounts of quaternary carbons are the most "medically" inert. See column 3, lines 60+ within Pinchuk ('240) and page 3, lines 36-36 of EP 821,973. Furthermore, Kennedy teaches the use of polyols that are in rich quaternary carbons to produce polyurethanes. See column 1, lines 6-31; column 5, and column 10, lines 24+ within Kennedy. Therefore, in view of these secondary teachings disclosing the medical benefits of incorporating quaternary carbons into the polymer chain and the known use of such quaternary carbon group-containing reactants to produce polyurethanes, the position is taken that one of ordinary skill, seeking a biostable polymer, would have been motivated to incorporate the polyol of Kennedy into the polymers of the primary references, so as to obtain a medically improved polymer having an elevated amount of quaternary-carbon containing groups. In view of the definitions of the variables for the structure of applicants' claims, the position is taken that there is no requirement that the claimed quaternary carbons and silicon-containing groups stem from a single reactant.

20. Applicants' arguments have been addressed within paragraph 17.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

RABON SERGENT
PRIMARY EXAMINER

R. Sergent
May 12, 2007